IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF DR. JIMMY W. MAYS

Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"), submit this memorandum in support of their motion to exclude the opinions and testimony of Dr. Jimmy W. Mays, Ph. D. ("Dr. Mays"). The cases to which this motion applies are identified on Ex. A to this motion.

INTRODUCTION

Plaintiffs have designated Dr. Mays to offer general causation opinions regarding the alleged oxidative degradation of the Prolene polypropylene in pelvic mesh products manufactured by Ethicon, including TVT, TVT-O, TVT-Secur, TVT Abbrevo, TVT Exact, Gynemesh PS, Prolift, Prolift+M, and Prosima (collectively, "Ethicon Mesh Products"). Ex. B, Expert Report of Jimmy W. Mays ("Mays Report").

This Court has previously ruled on the admissibility of Dr. Mays's degradation opinions in the context of pelvic mesh litigation against the Boston Scientific Corporation. In those cases, the Court repeatedly excluded Dr. Mays's opinions based on various tests he conducted on polypropylene manufactured by Boston Scientific. *See Frankum v. Bos. Sci. Corp.*, No. 2:12-cv-00904, 2015 WL 1976952, at **14-15 (S.D. W. Va. May 1, 2015); *Eghnayem v. Boston Sci.*

Corp., 57 F. Supp. 3d 658, 685-91 (S.D. W. Va. 2014); *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at **24-29 (S.D.W. Va. Sept. 29, 2014).

Although the Court has previously permitted Dr. Mays to testify based on his literature review, the opinions he seeks to offer in this litigation nonetheless warrant exclusion. Specifically, the Court should exclude Dr. Mays's degradation opinions in this litigation because they are unsupported by testing or scientific literature regarding the substance at issue in this litigation—the Prolene used in Ethicon Mesh Products.

The Court has previously questioned the validity of Ethicon's position that Prolene has chemical characteristics that make it materially distinct from other forms of polypropylene. *See Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014). But since that time, Plaintiffs' experts have admitted that Prolene is unique. *See, e.g.,* Ex. C, *Huskey* 8/25/2014 Trial Tr. 156:14–18; 157:11–17 (Dr. Guelcher testifying that Prolene is different from the polypropylene in other medical devices due to its antioxidant package); Ex. D, Guelcher 3/23/16 Dep. Tr. 87:23-88:9 ("Guelcher Dep. Tr.") (Dr. Guelcher conceding that Prolene is different than other forms of polypropylene); Ex. E, Priddy 3/8/16 Dep. Tr. 103:11-104:13 ("Priddy Dep. Tr.") (Dr. Priddy admitting that Prolene's additives set it apart from generic polypropylene). Indeed, Dr. Mays conceded at deposition that Prolene's antioxidant package distinguishes it, not only from pure polypropylene, but other forms of commercial polypropylene, as well. Ex. F, Mays 3/2/16 Dep. Tr. 30:15-24 ("Mays Dep. Tr.") (explaining that "Prolene is a particular formulation of polypropylene" with "different additives," "different molecular weights" and "different molecular weight distributions").

Despite recognizing the singularity of Prolene, Dr. Mays did not conduct testing to support his opinions in this litigation. And while he seeks to base his opinions on his review of

scientific literature, none of the materials to which he cites support the proposition that the Prolene used in Ethicon Mesh Products degrades in the human body. Accordingly, the Court should exclude Dr. Mays's opinions in their entirety.

In addition, the Court should preclude Dr. Mays from opining about the clinical complications allegedly caused by degradation. Dr. Mays lacks the qualifications necessary to offer such opinions, and fails to ground his opinions in reliable medical literature.

Finally, the Court should preclude Dr. Mays from testifying about Ethicon's knowledge, state of mind, and corporate conduct, as well as offering opinions that are nothing more than legal conclusions. This Court has repeatedly ruled that such testimony invades the province of the trier-of-fact, and Dr. Mays's opinions should be excluded on that basis.

ARGUMENT

I. Legal Standard

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3, (S.D. W. Va. July 8, 2014).

II. Dr. Mays's Degradation Opinions Are Unreliable.

Dr. Mays's central opinion in this litigation is that the Prolene used in Ethicon Mesh Products is subject to oxidation and degradation. But, even though he recognized that Prolene is different than other forms of polypropylene, Ex. F, Mays Dep. Tr. 30:15-31:13, Dr. Mays failed to test Prolene or base his opinions on reliable scientific literature specifically addressing Prolene.

A. Dr. Mays Admits That Prolene is Unique.

At deposition, Dr. Mays conceded that Prolene is different than other forms of polypropylene. *Id.* at 30:15-31:13. Specifically, Dr. Mays testified that, although polypropylene

is the base component in all forms of polypropylene, there are "different additives . . . different molecular weights of polypropylene . . . [and] different molecular weight distributions of the polypropylene that's used," which render Prolene a "particular formulation of polypropylene." *Id.* at 30:18-24. Although the Court has previously questioned Ethicon's position that Prolene is distinct from other forms of polypropylene, *Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014), the evidence in this litigation—including the testimony of Plaintiffs' experts, such as Dr. Mays—demonstrates that Prolene is not merely a brand name for a commodity. *See, e.g.*, Ex. C, *Huskey* 8/25/2014 Trial Tr. 156:14–18; 157:11–17; Ex. D, Guelcher Dep. Tr. 87:23-88:9; Ex. E, Priddy Dep. Tr. 103:11-104:13; Ex. F, Mays Dep. Tr. 30:15-24. Rather, Prolene is a unique chemical formulation of polypropylene with distinct properties.

It is inconsistent with the "intellectual rigor" employed by polymer chemists to make conclusions about the characteristics and behavior of a specific substance—here, Prolene—in the absence of testing or scientific literature addressing that substance. *Marsh v. W.R. Grace & Co.*, 80 F. App'x 883, 886 (4th Cir. 2003) ("goal of the *Daubert* analysis is to ensure that 'an expert, whether basing his testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'").

B. Dr. Mays Did Not Test Prolene To Support His Degradation Opinions.

Dr. Mays testified at deposition that it is necessary to conduct testing, such as spectroscopy and molecular weight analysis, to determine whether a material has degraded. *Id*. at 47:16-49:7. The importance of such testing to Dr. Mays's degradation opinions is evidenced by his efforts in pelvic mesh litigation against other manufacturers. *See, e.g., Frankum v. Boston Sci. Corp.*, No. 2:12-cv-00904, 2015 WL 1976952, at **14-15 (S.D. W. Va. May 1, 2015) (excluding Dr. Mays's thermogravimetric analysis as unreliable and irrelevant); *Eghnayem v.*

Boston Sci. Corp., 57 F. Supp. 3d 658, 685-91 (excluding Dr. Mays's microscopic and chemical testing of Boston Scientific polypropylene meshes as unreliable because it (i) failed to control for error or bias, and (ii) did not establish or adhere to tresting protocols); *see also* Ex. F, Mays Dep. Tr. 55:3-21 (testifying about his testing of Boston Scientific meshes to assess degradation). In addition, Dr. Mays agreed that it would be important to his opinions in this litigation to review any available explants and histological slides. *Id*. at 41:15-20; 42:4-11.

Although Dr. Mays seeks to opine that the Prolene in Ethicon mesh products is subject to oxidative degradation, he admitted that he has never conducted any tests on Prolene. *Id*. at 34:13-35:10. Specifically, Dr. Mays admitted that he never tested Prolene to determine if it degrades or experiences a reduction in mechanical properties. *Id.* at 34:13-20. He never tested the durability, tensile strength, toughness, or any other physical property of Prolene. *Id.* at 36:8-19. Nor has he ever run any type of oxidation test on Prolene. *Id.* at 44:8-10.

Despite his testimony that a review of Prolene mesh explants and histological slides would be important to his opinions in this litigation, *id.* at 41:15-20; 42:4-11, Dr. Mays made no effort to conduct any such analysis, *id.* at 41:21-42:11. Indeed, Dr. Mays has never inspected any Prolene mesh explant, *id.* at 22:2-4, much less a Prolene explant that had oxidized or degraded, *id.* at 35:11-17. Nor has he ever seen a Prolene explant that had become embrittled or undergone a reduction of any physical property. *Id.* at 35:18-36:7.

C. The Scientific Literature On Which Dr. Mays Relies Does Not Support His Degradation Opinions.

Having failed to conduct any tests on Prolene, Dr. Mays seeks to base his degradation opinions on his review of scientific literature and certain internal Ethicon documents. Ex. F, Mays Dep. Tr. 37:18-38:1; *see also* Ex. B, Mays Report at 14-26. But none of the materials to

which he cites actually stands for the proposition that the Prolene in Ethicon mesh products oxidizes and degrades *in vivo*.

1. Dr. Mays relies on studies that either do not assess Prolene implanted in the female pelvic floor or are methodologically unsound.

Many of the studies on which Dr. Mays relies do not support his degradation opinions because they do not address Prolene. *See* Ex. B, Mays Report at 14-24 (discussing papers by Liebert, Postlewait, Bracco, Clave, Lefranc, Imel, and Ostergard[1]). Again, it cannot be said that offering an opinion based on studies that do not address the subject matter of the opinion—Prolene—is consistent with the "intellectual rigor" employed by polymer chemists. *See Marsh*, 80 F. App'x at 886.

Even where Dr. Mays points to literature that addresses Prolene, the studies do not support his degradation opinions. At deposition, Dr. Mays testified that the only peer-reviewed literature analyzing Prolene on which he relies in this litigation are studies by Jongebloed, Costello, and Mary. Ex. F, Mays Dep. Tr. 47:12-15.[2] But scrutiny of these studies reveals that

[1] Dr. Mays quotes liberally from a paper by Dr. Donald Ostergard—a urogynecologist who is a paid expert for plaintiffs in pelvic mesh litigation—that contains no testing, but purports to define when the FDA and mesh industry had knowledge of the alleged degradation of pelvic mesh. Ex. B, Mays Report at 23; *see also* Ex. G, D. Ostergard, *Degradation, Infection and Heat Effects on Polypropylene Mesh for Pelvic Implantation: What Was Known and When It Was Known*, 22 Int. Urogynecol. J. 771 (2011). But the fact that Dr. Ostergard's timeline was published does not permit Dr. Mays to circumvent the well-settled rule that an expert cannot testify about corporate knowledge or summarize documents for the jury. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009).

[2] Although he declined to rely on it at deposition, Dr. Mays's Report identifies a paper by Dr. Vladimir Iakovlev that purportedly "observed a degradation layer or 'bark' and . . . proposed oxidative degradation as a mechanism consistent with their results." Ex. B, Mays Report at 22. Notably, this paper is based on the unreliable methods employed by Dr. Iakovlev, whose degradation hypothesis has been disproven. *See* Mem. Supp. Mot. Exclude Dr. Iakovlev, 6-7 *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, No. 2:12-cv-01267.

they simply do not stand for the proposition that Prolene implanted in the female pelvic floor is subject to degradation.

Exposure to Conditions Not Found in the Pelvic Floor. Dr. Mays seeks to rely on two studies by Jongebloed as evidence that Prolene exhibits surface degradation after implantation. *See* Ex. B, Mays Report at 15; *see also* Ex. H, W. Jongebloed & J. Worst, *Degradation of Polypropylene in the Human Eye: A SEM Study*, 64 Documenta Opthamologica 143 (1986); Ex. I, W. Jongebloed, *et al.*, *Mechanical and Biomechanical Effects of Man-Made Fibres and Metals in the Human Eye: A SEM Study*, 61 Documenta Opthamologica 303 (1986). These studies are inapposite because they both addressed sutures that had been implanted in the human eye.

It is undisputed that all forms of polypropylene—including Prolene—are subject to oxidation when exposed to ultraviolet radiation. Thus, the fact that ocular sutures—which would necessarily be exposed to ultraviolet radiation—oxidize after implantation in the eye is neither surprising nor germane to the Prolene used in Ethicon mesh products placed in the female pelvic floor.

Not Prolene and Speculative. Dr. Mays seeks to base his degradation opinions on two studies by Costello. Ex., B, Mays Report at 16; *see also* Ex. J, C.R. Costello, *et al.*, *Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants From a Single Patient*, 14 Surg. Innov. 168 (2007) ("Single Patient"); Ex. K, C.R. Costello, *et al.*, *Materials Characterization of Explanted Hernia Meshes*, 83B J. Biomed. Mater. Res Part B: Appl Biomater 44 (2007) ("Materials Characterization"). For instance, Dr. Mays seeks to inform the jury that the study found that "[c]racks and other surface degradations such as peeling of the fibers are indicative of the oxidation of polymeric materials." Ex. B, Mays Report at 16 (quoting Single Patient, at 175). Dr. Mays also reports that Costello concluded that "[p]olypropylene is

highly susceptible to the oxidative effects of the metabolites produced by phagocytic cells during the inflammatory response." *Id.*

As an initial matter, the Materials Characterization study analyzed only mesh manufactured by C.R. Bard, and not the Prolene at issue in this litigation. For this reason, the findings of this study simply do not apply to Prolene. *See* Ex. F, Mays Dep. Tr. 30:18-24.

Although the Single Patient study involved a polypropylene mesh manufactured by Ethicon, closer scrutiny of the study demonstrates that it does not support Dr. Mays's opinion. The Single Patient study analyzed three different hernia mesh explants: (i) Gore-Tex; (ii) a heavyweight polypropylene mesh manufactured by Bard; and (iii) Proceed, an Ethicon mesh composed of Prolene coated with oxidized cellulose. Ex J, Single Patient, at 169-70. Although the study found substantial evidence of oxidation and degradation of the Bard mesh, it reported no such evidence for the Proceed mesh. Ex. J, Single Patient at 172-75.[3] In fact, in the same paragraph from which Dr. Mays quotes about the degradative propensity of polypropylene, Ex. B, Mays Report at 16, the Single Patient study reports that the Proceed "specimen did not possess any visible surface degradation," Ex. J, Single Patient at 175. Thus, all of the findings reported by the Single Patient study about the degradation of polypropylene—that Dr. Mays seeks to attribute to Prolene in this litigation—are actually limited to the heavyweight mesh manufactured by Bard.

Unreliable methodology. Dr. Mays points to a study by Mary to support his opinion that Prolene undergoes oxidative degradation. Ex. B, Mays Report at 15-16; Ex. L, C. Mary, *et al.*,

[3] Indeed, the Single Patient study reported that scanning electron microscopy "revealed features identical to those of the pristine" Prolene Soft comparator, *id.* at 172; differential scanning calorimetry testing showed no statistically significant difference in melting temperature, *id.* at 173; thermogravimetric analysis testing showing "almost identical" values for the Proceed explant and pristine Prolene Soft sample, *id.* at 174; and histological examination revealed "minimal fibrotic tissue around the mesh" explant composed of Proceed, *id.* at 174.

Comparison of the In Vivo *Behavior of Polyvinylidene Flouride and Polypropylene Sutures Used in Vascular Surgery*, 44 Am. Soc'y Articial Internal Organs J. 199 (1998) ("Mary Study"). But the Mary Sudy's results were the product of an unreliable methodology.

Notably, the authors did not conduct any molecular weight analysis or test the mechanical properties of the sutures. Rather, the Study concluded that the Prolene sutures had oxidized based on FTIR test results showing a peak at 1,740^{cm-}, which "has been assigned to carbonyl stretching, and identifies the presence of surface oxidation, because the chemical structure of both pure polymers are devoid of this functional group." Ex. L, Mary Study at 201. But as Dr. Mays admitted at deposition, the authors did not recognize in the study that 1,740^{cm-} is also the wavelength for one of the antioxidants used in Prolene. Ex. F. Mays Dep. Tr. 123:7-124:10. Thus, the study failed to determine whether the peak at 1,740^{cm-} was merely a reading of the antioxidant package used in Prolene.

In addition, the sample preparation process used in the Mary study introduced error into the SEM results. Specifically, the study explains that after explantation, the sutures designated for SEM analysis were treated with either formalin or gluteraldehyde prior to cleaning. Ex. L, Mary Study at 200. The study ignores the fact that both formalin and gluteraldehyde crosslink with the proteinaceous layer on the fibers to form a hardened shell that can manifest as a cracked layer under SEM. *See* Ex. M, Expert Report of Shelby Thames, at 10, 16-21 (explaining that fixative agents used in sample preparation—formalin, formaldehyde, etc.—bond or crosslink with proteins adhered to the surface of an explant to form a hard, insoluble, and brittle shell around the surface of the explant).

2. Dr. Mays relies on unpublished Ethicon documents regarding Prolene sutures that do not support his opinion and would be highly prejudicial unless Ethicon can introduce evidence that the FDA approved Prolene sutures for use in the human body.

Dr. Mays also seeks to support his opinion that Prolene is subject to degradation by referring to certain unpublished Ethicon documents regarding Prolene sutures. Ex. B, Mays Report at 24-26. Yet, these internal documents do not support Dr. Mays's degradation opinions. In the event the Court permits Dr. Mays to testify based on his review of Ethicon's internal studies, the Court should allow Ethicon to introduce evidence regarding the FDA approval and regulation of Prolene polypropylene sutures.

a. Ethicon's unpublished studies do not support Dr. Mays's degradation opinions.

Dr. Mays bases his opinion that Prolene degrades such that it has diminished physical properties on a 1983 Prolene suture study. Ex. B, Mays Report at 24; Ex. F, Mays Dep. Tr. 99:2-8; *see also* Ex. N, B. Matlaga Ltr. to Dr. A. Lunn (Mar. 23, 1983), ETH.MESH.15955438-73. But Dr. Mays admitted at deposition that the 1983 suture study only examined one fiber explant. Ex. F, Mays Dep. Tr. 99:9-100:8. He also conceded that he could not rule out the possibility that the fiber analyzed in the study was damaged during excision. *Id.* at 100:23-101:4.

Dr. Mays also points to Ethicon's 1987 Prolene suture study as evidence that Prolene is subject to oxidative degradation. Ex. B, Mays Report at 25; *see also* Ex. O, IR Microscopy of Explanted Prolene (Sept. 30, 1987), ETH.MESH.12831391–1404. But the 1987 suture test does not support Dr. Mays's opinion that Prolene is subject to *in vivo* degradation, because it did not report a change in molecular weight in the sutures, which Plaintiffs' experts—including Dr. Mays—have acknowledged is a fundamental component of oxidative degradation. *See* Ex. F, Mays Dep. Tr. 79:3-80:12 ("Q. But, Doctor, for oxidative degradation to occur, there must be

loss of molecular weight, correct? A. Yes, when oxidative degradation occurs, there is degradation of molecular weight."); *see also* Ex. P, Jordi 10/30/13 Dep. Tr. 173:25–174:8 (admitting that test results showing no loss of molecular weight suggests that there is no degradation of polypropylene). Nor did the study make any findings that the sutures' mechanical properties—such as elongation and tensile strength—diminished.

Similarly, Dr. Mays relies on Ethicon's seven-year dog study of Prolene sutures as proof that Prolene oxidizes and degrades *in vivo*. Ex., Q, Seven Year Data for Ten Year Prolene Study (Oct. 15, 1992), ETH.MESH.09888220. But his reliance on the seven-year dog study is misplaced, because he admitted that it reported insignificant changes of molecular weight and "no molecular weight degradation." Ex. F, Mays Dep. Tr. 151:4-14. Dr. Mays also acknowledged that the study indicates that the sutures were plasticized *in vivo*, which would actually improve the toughness of the suture. *Id.* at 154:2-13.

Ultimately, none of these internal Ethicon documents supports Dr. Mays's opinion that the Prolene used in Ethicon Mesh Products degrades in the human body. Accordingly, the Court should exclude his opinions as unreliable.

b. If the Court permits Dr. Mays to testify based on Ethicon's testing of Prolene sutures, it should allow Ethicon to submit evidence of FDA's approval and regulation of Prolene sutures.

In addition, Ethicon submits that Dr. Mays should not be permitted to testify that Prolene degrades based on his review of these internal Ethicon documents which assess Prolene polypropylene sutures, unless Ethicon can introduce evidence regarding the FDA approval and regulation of the Prolene polypropylene sutures. As the Court is aware, the FDA approved Prolene polypropylene sutures as an implantable medical device when it approved the Prolene polypropylene suture New Drug Application in 1969. *See, e.g.*, Mem. Supp. Mot. Partial Summ. Judg. Based on Preemption [ECF No. 129], *Lewis v. Johnson & Johnson*, No. 2:12-cv-04301

(S.D. W. Va. Dec. 12, 2013), at 2–4. The FDA in 1988 approved labeling which said that the Prolene sutures were "not subject to degradation or weakening by the action of tissue enzymes." *Id*. From 1976 to 1990, the FDA regulated Prolene sutures as a Class III medical device subject to the Premarket Approval ("PMA") process. *See id.* at 4. In 1990, the FDA reclassified Prolene and other polypropylene sutures as a Class II device, subject to less rigorous controls, based on the proven safety and effectiveness of polypropylene sutures. *See id.* at 4–5.

As the Court has recognized, the FDA's PMA review is much more rigorous than the 510(k) process, and design-defect claims for PMA-approved devices are typically preempted. *See, e.g.*, *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014) (discussing differences between PMA and 510(k) processes and acknowledging that "tort claims regarding medical devices approved through the premarket approval process generally are preempted"). Thus, if the Plaintiffs were suing for alleged design defects in Prolene sutures, their claims would likely be preempted in light of the FDA's approval of these devices.

In prior cases in this MDL, the Court has consistently excluded evidence of FDA actions. Assuming the Court maintains that approach here, Ethicon will be unduly prejudiced by any testimony from Dr. Mays regarding or based on the alleged *in vivo* degradation of Prolene sutures. Otherwise, Dr. May would be free to testify that Prolene sutures degrade *in vivo*, but Ethicon would be unable to rebut this opinion with evidence that the FDA specifically approved Prolene for use in sutures and considered Prolene and other polypropylene sutures to be free from harmful degradation and safe and effective for use in the human body.

III. The Court Should Exclude Dr. Mays's Opinions Regarding Clinical Complications Allegedly Caused By Degradation.

Dr. Mays seeks to inform the jury that the Prolene in Ethicon Mesh Products is subject to oxidative degradation following implantation, and this degradation causes the mesh to stiffen,

which "can lead to pain, inflammation, and tissue damage in patients implanted with the device." Ex. B, Mays Report at 27. Furthermore, Dr. Mays seeks to opine that degraded Prolene is "behind all [mesh] removals" and "at the heart of the problems that all of [the plaintiffs in this litigation] had." Ex., F, Mays Dep. at 50:8-10.

But Dr. Mays is not a medical doctor. *Id.* at 53:7. He is not a clinician. *Id.* at 52:23-24. Rather, he is a polymer chemist whose qualifications lie not in diagnosis of clinical complications, but in the "characterization of polymers[.]" *Id.* at 53:5-7. Dr. Mays's lack of qualifications to offer opinions regarding the clinical complications allegedly caused by degradation is, by itself, a sufficient basis for the Court to exclude his testimony on these issues. *See, e.g., Hines v. Wyeth,* No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011) (excluding expert testimony that went "beyond the experts' qualifications").

Even if Dr. Mays was qualified to offer opinions regarding medical causation—and he is not—there is no suggestion in Dr. Mays's Report or deposition transcript that he has ever conducted the differential diagnoses necessary to determine whether a patient's mesh caused clinical symptoms like pain, dyspareunia, or any other complications. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) (explaining that a "[d]ifferential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated."). Nor has he reviewed any medical records or spoken to any physicians such that he could opine that patients actually suffer from the clinical complications about which he seeks to testify. *See, e.g.*, Ex. F, Mays Dep. Tr. 39:20-23.

Finally, Dr. Mays cannot base his opinions regarding complications on scientific or medical literature. At deposition, Dr. Mays conceded that he could only identify two sources of

support for his opinion that the degradation of Prolene causes clinical complications: (i) a textbook by Professor David Williams, and (ii) a study by Dr. Uwe Klinge. *Id*. at 59:5-17, 60:8-18. But Dr. Mays admitted that the Williams text does not actually address Prolene. *Id.* at 59:18-20.

Similarly, a review of the Klinge study reveals that while it involved a mesh manufactured by Ethicon, it analyzed a multifilament hernia mesh that had been treated with polyglactin 910, not the Prolene monofilament used in the Ethicon Mesh Products at issue in this litigation. *See* Ex. R, U. Klinge, *et al.*, *Shrinkage of Polypropylene Mesh* In Vivo: *An Experimental Study in Dogs*, 164 Eur. J. Surgery. 965, 965 (1998). In addition, the Klinge study actually reported that the Ethicon hernia mesh elicited an inflammatory response that "was considerably less" than the Marlex mesh to which it was compared. *Id.* at 967. The study also found "moderate" fibrosis, "no scar plate," "few fibroblasts," and "increased vascularization." *Id.* In other words, the Klinge study simply does not support Dr. Mays' opinion that the degradation of Prolene in Ethicon Mesh Products used in the female pelvic floor causes clinical complications in the human body.

The Court should preclude Dr. Mays from testifying about complications allegedly caused by degradation because he is not qualified to offer such opinions and his opinions are not based in scientific or medical evidence.[4]

[4] Notably, Dr. Mays did not inform physicians at the University of Tennessee—where he is employed—about his views regarding the alleged risks associated with using any polypropylene-based pelvic mesh until after he was cross-examined about his prior failure to do so. Ex. F, Mays Dep. Tr. 57:16-58:2. He admitted that he has never shared his views about Prolene with his colleagues. *Id.* at 58:16-19.

IV. The Court Should Preclude Dr. Mays From Offering Opinions Regarding Ethicon's Knowledge, State of Mind, or Corporate Conduct, as Well as His Legal Conclusions Masquerading as Expert Opinions.

Throughout his Report, Dr. Mays offers opinions that exceed the scope of proper expert testimony. For instance, Dr. Mays offers various opinions regarding Ethicon's alleged knowledge, state of mind, or corporate conduct. By way of example, Dr. Mays asserts that "Ethicon was aware of the oxidation of Prolene prior to the introduction of the transvaginal mesh devices . . . but the company did not consider the risks associated with polypropylene oxidation[.]" Ex. B, Mays Report at 5; *see also id.* ("Ethicon did not take into account polypropylene's propensity for oxidation during [the] design of its various Prolene based mesh products."); 24 ("Ethicon was sufficiently aware of Prolene surface cracking and concerned enough about the consequences to form a committee to investigate the mechanism of cracking."). But, as this Court has repeatedly held, a corporate defendant's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *See, e.g., In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013).[5]

Dr. Mays also seeks to offer legal conclusions in the guise of expert opinions. For example, Dr. Mays claims that "Prolene mesh is unreasonably dangerous, defective and is not suitable to serve as the permanent implants that they have been represented by Ethicon to be." Ex. B, Mays Report at 6; *see also id.* at 22 (contending that the "change in materials properties of a material implanted in the female pelvis poses unreasonable risk of harm and is defective from a

[5] Dr. Mays also lacks the qualifications to offer opinions regarding Ethicon's corporate knowledge or conduct. Dr. Mays is a polymer chemist. His resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at 9 (E.D. Pa. June 20, 2000).

design perspective in terms of the material choice made by Ethicon."); *id.* at 27 (asserting that Ethicon mesh products are "unreasonably dangerous to sell for the uses Ethicon sold [them] for," and that Ethicon "was unreasonable . . . to sell these devices for the intended applications."). As this Court has recognized, "'opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.'" *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 186872, at *21 (S.D.W. Va. Jan. 15, 2014).

Dr. Mays also seeks to support his degradation opinions by spending several pages of his Report presenting his interpretation of a series of Ethicon's internal documents. *See id.* at 24-26. But expert witnesses are not "permitted to merely read, selectively quote from, or 'regurgitate' the evidence" because a jury is more than capable of reading and summarizing documents on its own. *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009); *see also In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 880 (E.D. Ark. 2008) (striking improper expert's testimony that "simply . . . regurgitate[ed] . . . an exhibit, absent any expert analysis or opinion"), *aff'd in pertinent part*, 586 F.3d 547, 571 (8th Cir. 2009). Accordingly, the Court should preclude Dr. Mays from testifying as to the content of Ethicon's internal documents.

For all of the reasons set forth above, the Court should preclude Dr. Mays from offering a narrative summary of Ethicon's documents or opinions concerning Ethicon's purported knowledge, state of mind, and corporate conduct. The Court should also bar Dr. Mays from presenting legal conclusions to the jury.

V. Conclusion

For the foregoing reasons, Ethicon requests that the Court exclude the opinion testimony of Dr. Mays, and grant such other and further relief as the Court deems proper under the circumstances.

Respectfully submitted,

/s/ Susan M. Robinson
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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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